

#31

UNITED STATES DISTRICT COURT
District of Columbia

The Regents of the UNIVERSITY OF
CALIFORNIA,

SUMMONS IN A CIVIL CASE

V.

HONORABLE JAMES E. ROGAN, UNDER SECRETARY
OF COMMERCE FOR INTELLECTUAL PROPERTY
AND DIRECTOR OF THE USPTO,
United States Patent and Trademark Office
Office of the General Counsel
Crystal Park Two, Suite 905
2121 Crystal Drive
Arlington, Virginia 22202

CASE NUMBER:

CASE NUMBER 1:03CV01133
JUDGE: Richard W. Roberts
DECK TYPE: General Civil
DATE STAMP: 05/27/2003

TO: (Name and address of Defendant)

Civil Process Clerk
U.S. Attorney's Office
District of Columbia
Judiciary Center
555 Fourth Street, NW
Washington, DC 20530

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Stephen Colangelo
Morrison & Foerster LLP
1650 Tysons Boulevard
Suite 300
McLean Virginia 22102

an answer to the complaint which is served on you with this summons, within 20 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

CL 6/4/03

NANCY HAYER WHITTINGTON

CLERK

[Signature]
(By) DEPUTY CLERK

MAY 27 2003

DATE

RETURN OF SERVICE

Service of the Summons and complaint was made by me ⁽¹⁾	DATE
NAME OF SERVER (PRINT)	TITLE

Check one box below to indicate appropriate method of service

G Served personally upon the defendant. Place where served: _____

G Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein.

Name of person with whom the summons and complaint were left: _____

G Returned unexecuted: _____

G Other (specify): _____

STATEMENT OF SERVICE FEES

TRAVEL	SERVICES	TOTAL
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DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.

Executed on _____
Date_____
Signature of Server_____
Address of Server

(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

icy M. Mayer-Whittington
rk of Court

**NOTICE OF RIGHT TO CONSENT TO TRIAL
BEFORE A UNITED STATES MAGISTRATE JUDGE**

The substantial criminal caseload in this Court and the requirements of the criminal Speedy Trial Act frequently result in the delay in the trial of civil cases. Aware of the hardship and expense to the parties, counsel, and witnesses caused by the delays which are beyond the control of the Court, this notice is to advise you of your right to trial of your case by a United States Magistrate Judge. By statute, 28 USC § 636(c), Fed.R.Civ.P. 73 and Local Civil Rule 73.1, the parties, by consent, can try their case by means of a jury trial or bench trial before a United States Magistrate Judge. Appeals from judgments and final orders are taken directly to the United States Court of Appeals for the District of Columbia Circuit, in the same manner as an appeal from a judgment of a District Judge in a civil case.

WHAT IS THE PROCEDURE?

One of the matters you are required to discuss at the meet-and-confer conference mandated by Local Civil Rule 16.3 is whether the case should be assigned to a United States Magistrate Judge for all purposes, including trial

All parties must consent before the case is assigned to a Magistrate Judge for trial. You may consent at any time prior to trial. If you expressly decline to consent or simply fail to consent early in the case, you are not foreclosed from consenting later in the case. However, a prompt election to proceed before a Magistrate Judge is encouraged because it will facilitate a more orderly scheduling of the case.

Counsel for the plaintiff has been furnished a copy of the "Consent to Proceed Before a United States Magistrate Judge for all Purposes" form. If and when the form is executed, your response should be made to the Clerk of the United States District Court only.

WHAT IS THE ADVANTAGE?

The case will be resolved sooner and less expensively. The earlier the parties consent to assigning the case to a Magistrate Judge the earlier a firm and certain trial date can be established, even if the case is to be tried to a jury.

Upon the filing of the consent form and with the approval of the District Judge, the case will be assigned to all purposes to a Magistrate Judge.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE REGENTS OF THE UNIVERSITY OF
CALIFORNIA,

111 Franklin Street
Oakland, California 94612-3550

Plaintiff,

v.

HONORABLE JAMES E. ROGAN, UNDER
SECRETARY OF COMMERCE FOR
INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES
PATENT AND TRADEMARK OFFICE,

United States Patent and Trademark Office
Office of the General Counsel
Crystal Park Two, Suite 905
2121 Crystal Drive
Arlington, Virginia 22202

Defendant.

CASE NUMBER 1:03CV01133

JUDGE: Richard W. Roberts

No. DECK TYPE: General Civil

DATE STAMP: 05/27/2003

**COMPLAINT FOR REVERSAL OF A DECISION OF THE UNITED
STATES PATENT AND TRADEMARK OFFICE BOARD OF APPEALS
PURSUANT TO 35 U.S.C. § 145**

Plaintiff, THE REGENTS OF THE UNIVERSITY OF CALIFORNIA ("Plaintiff" or
"The Regents") for its Complaint against defendant alleges as follows:

THE PARTIES

1. This civil action is brought by Plaintiff against the Director of United States
Patent and Trademark Office for a judgment that Plaintiff is entitled to a patent pursuant to 35
U.S.C. § 145.

2. Plaintiff The Regents of the University of California is the assignee and owner of the entire right, title and interest in and to United States Patent Application Serial No. 08/487,312, entitled "Bovine Growth Hormone" (hereinafter the "'312 application") by assignment from the inventors Drs. Walter L. Miller, Joseph A. Martial, and John D. Baxter. The Regents is a public corporation under the laws of the State of California operating under Article 9, Section 9 of the California Constitution, having its principal place of business at 111 Franklin Street, 12th Floor, Oakland, California 94612-3550.

3. Defendant the Honorable James E. Rogan is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (hereinafter "PTO"), who in his official capacity as Director of the PTO is a legal resident of the District of Columbia and within the jurisdiction of this Court. Mr. Rogan is hereby sued in his official capacity as Director pursuant to 35 U.S.C. § 145.

JURISDICTION AND VENUE

4. This is an action by patent owners dissatisfied with the decision of the Board of Patent Appeals and Interferences in the examination of the '312 application. Jurisdiction and venue are proper in this Court pursuant to 35 U.S.C. § 145 and, in the alternative, 28 U.S.C. §§ 1338 and 1391.

THE ACTION

5. The '312 application discloses and claims inventions related to the production of bovine growth hormone using recombinant techniques. Bovine growth hormone (bGH) is a hormone that stimulates milk production in cows. The '312 application is one of a family of applications that claim technology relating to inventions regarding recombinant bGH made at the University of California San Francisco in the very late 1970s. The '312 application relates specifically to claims to bGH produced by recombinant means.

6. The '312 application was filed in the PTO on June 7, 1995. The '312 application is a continuation of United States Patent Application Serial No. 07/480,745, filed February 15, 1990, which is a continuation of United States Patent Application Serial No. 07/090,937, filed August 28, 1987, which is a continuation of United States Patent Application Serial No. 06/489,557, filed April 28, 1983, which is a continuation of United States Patent Application Serial No. 06/181,348, filed August 26, 1980. The '312 application is entitled to the benefit of the August 26, 1980 filing date of the 06/181,348 application pursuant to 35 U.S.C. § 120.

7. The '312 application was filed in accordance with the laws of the United States and the rules of the PTO and was duly prosecuted before the PTO.

8. Plaintiff is entitled to a United States Patent for the inventions claimed in the '312 application.

9. All three pending claims—claims 19, 20 and 22—of the '312 application were finally rejected by the Examiner in charge of the application at the PTO on October 16, 1996.

10. Plaintiff appealed the final rejection to the Board of Patent Appeals and Interferences (hereinafter the "Board") on January 16, 1997. Briefing was completed on October 15, 1997. On March 26, 2003, more than six years after the appeal was taken, the Board rendered its decision.

11. In error, the Board affirmed the final rejection of the Examiner. Specifically, the Board found in error that the claims were not novel pursuant to 35 U.S.C. § 102, or in the alternative, were obvious pursuant to 35 U.S.C. § 103 based on the disclosures in United States Patent No. 3,265,579 issued to Edward G. Daniels and Alan J. Parcellas, entitled "Process For Purification of Bovine Growth Hormone" (hereinafter "Daniels").

12. In its decision, the Board was unable to consider important evidence regarding facts that came to light after prosecution was closed, and the Board did not have access to additional evidence that supports Plaintiff's position before the Board. Plaintiff brings this action to provide the evidence that was not available in the record before the PTO, to obtain a *de*

novo review based on the expanded factual record, and to obtain a determination that Plaintiff is entitled to a patent for the invention claimed in the '312 application.

13. Due to changes in the patent laws after June 8, 1995 based on the GATT/TRIP agreements, Plaintiff is foreclosed from providing new evidence in connection with a re-filed (continuing) application because any patent issued on such application would expire before it issues.

14. Plaintiff has petitioned the PTO to reopen prosecution of the application to permit it to provide new evidence that it was unable to submit during prior prosecution and to address questions raised by the Board. The petition has not been granted by the Director as of the date of the filing of this Complaint.

15. No appeal to the United States Court of Appeals for the Federal Circuit has been taken from the decision of the Board.

FACTUAL BACKGROUND

BOVINE GROWTH HORMONE

16. Mammals use a variety of protein hormones to regulate various biological functions, including growth. Many systemic hormones are created in the pituitary gland, a gland that is located below and in contact with the brain in most mammals. Growth hormone, including bGH, is one of these.

17. bGH is responsible for growth hormone functions in cows. It is a protein of 191 amino acids in length that is encoded by a distinct gene in a cow's genome or DNA. It affects various biological functions in cows, including milk production. The recombinant form of this hormone is used to enhance the productivity of United States farms. The recombinant form of this protein, rather than bGH extracted from pituitaries, must be used for this purpose as explained below.

MAD COW DISEASE

18. Bovine spongiform encephalopathy ("BSE"), commonly known as Mad Cow Disease, is a fatal disorder that causes progressive neurological degeneration in cattle. BSE was first reported among cows in the United Kingdom in November 1986. BSE is transferred to unaffected livestock when they are fed materials derived from an animal that has BSE, particularly if these materials are derived from the nervous system, brain, brain stem or surrounding tissue of cows, as is the case for bGH derived from pituitaries. These materials contain the infectious agent for BSE. There is no known treatment for BSE.

19. Creutzfeldt-Jakob disease ("CJD") is the human counterpart to BSE. CJD is invariably fatal with no known treatment or cure. There exists strong epidemiologic and laboratory evidence that a form of CJD can be transferred to humans by consumption of meat contaminated with agents that cause BSE. CJD acquired in this manner is known as new variant CJD or "vCJD." As of May 2003, there were approximately 96 confirmed deaths resulting from vCJD, approximately 33 probable but unconfirmed deaths resulting from vCJD, and approximately 6 cases of individuals currently infected with vCJD.

20. Consistent with the foregoing, CJD has also been transferred to humans in the past through the administration to children of preparations of human growth hormone (hGH) purified from pituitaries of human cadavers. As a result, the United States Food & Drug Administration and the National Institutes of Health stopped the administration of this purified hGH to patients in 1985. Treatment of growth deficiency has been continued by administering the recombinantly produced form of hGH instead, as this carries no risk of CJD.

21. Both BSE and CJD have long latency periods during which a cow or human may be infected but experience no symptoms. Nonetheless, there is no known test to identify the disease agent either in the body of a person or animal or in a test tube.

22. Europe has experienced several severe and debilitating outbreaks of Mad Cow Disease. An outbreak of Mad Cow Disease in the UK between 1986 and 2000 has had dramatic

consequences for the United Kingdom, where BSE is thought to have originated. In order to stem the BSE outbreak and avoid its economic effects, the government in the United Kingdom has slaughtered at least 3.3 million cattle between March 1996 and the end of 1999.

23. On May 20, the first case of BSE in North America in over ten years was reported by Canadian officials. Following the report that a single cow in Alberta was found to have the disease, the USDA immediately prohibited all importation of cattle from Canada, which is the largest exporter of beef to the United States. The threat posed by even this single event caused substantial declines in the stocks of companies that sell or render livestock, such as Tyson's Foods Corporation, or who depend heavily on the consumption of beef, such as the McDonald's Corporation.

24. To prevent any outbreak of BSE or vCJD in the United States, the United States Department of Agriculture strictly prohibits the use of any protein obtained from cattle in the manufacture of animal feeds given to ruminant animals such as cows, sheep and goats.

25. Because growth hormone purified from pituitaries is a known avenue for the transfer of the BSE infectious agent, it is inconceivable that bovine growth hormone purified from bovine pituitary glands would, or could ever be, used in the United States.

USE OF RECOMBINANT BOVINE GROWTH HORMONE IN THE UNITED STATES

26. In November 1993, the United States Food & Drug Administration approved the use of recombinant bovine growth hormone for use with livestock in the United States. This is the first form of bBH that had ever been approved for use with livestock in the United States. Plaintiff is informed and believes that the FDA would have denied approval for the drug if it were not produced by recombinant means.

27. Starting in 1994, Monsanto Corporation began to market the product under the trade name POSILACT™. Sales have grown significantly since that time. Plaintiff is informed and believes that Monsanto's sales of POSILACT™ have increased to between 200 and 600

million dollars per year. Monsanto's success with the product is the result of a significant demand for a recombinant growth hormone product for use by U.S. farmers. Substantial evidence of POSILAC™ success did not become available until after prosecution of the '312 was closed.

THE DANIELS PATENT

28. In 1966, Edward G. Daniels and Alan J. Parcellas obtained a United States Patent Number 3,265,579. The patent described a process for purifying bGH from bovine pituitary tissues. The patent did not claim purified bovine growth hormone, and nothing about the process as described would reliably exclude contaminants that could cause Mad Cow Disease.

29. A person of skill in the art that used the Daniels process could not provide any assurance that the end product would be free of contamination of agents that could cause Mad Cow Disease. Therefore, bGH produced by the Daniels process carries the inherent risk of the transmission of Mad Cow Disease.

BOVINE GROWTH HORMONE OBTAINED THROUGH RECOMBINANT TECHNOLOGY

30. The claims of the '312 application claim bGH produced by recombinant technology. Recombinant technology depends on the identification of part or all of a gene, portions of DNA that are the blueprint for the production of proteins. Once the blueprint is identified, recombinant technology allows scientists to combine the DNA into recombinant vectors or "plasmids" that can be used to introduce the DNA into unrelated organisms, including unicellular organisms such as bacteria. By appropriate methods, the new host cell or organism can be caused to produce the protein as a "living factory." The "living factory" can be chosen so that it is certain no infectious agents for mammalian diseases such as BSE and CJD are not present.

31. The inventors, Drs. Miller, Martial and Baxter, successfully identified DNA that encodes bovine growth hormone while at the University of California San Francisco. They also successfully combined this DNA into a recombinant plasmid and modified biological organisms so that they could successfully produce the bGH protein using the recombinant plasmids. The recombinantly produced hormone could be purified from these organisms using conventional techniques. The inventors described their invention and these techniques in the '312 application.

32. The foregoing techniques thus involve the transfer of DNA that encodes bGH into organisms that do not possess, and do not serve as hosts for, the agents that cause Mad Cow Disease. Accordingly, production of bovine growth hormone by these recombinant techniques inherently guarantees that the resulting preparation will not be contaminated by the agents that cause Mad Cow Disease.

33. Both in this and other ways, the bGH product of the recombinant process and the bGH product of the Daniels process differ in material and patentably distinct ways. Therefore, the claims of the '312 are neither anticipated by nor rendered obvious by the disclosures in the Daniels patent.

WHEREFORE, plaintiff respectfully prays for the entry of judgment:

- A. Reversing the Board of Patent Appeals and Interferences' affirmance of the Examiner's final rejection.
- B. Declaring that United States Letters Patent should issue for the inventions defined by claims 19, 20 & 22 of United States Patent Application Serial No. 08/487,312.
- C. Granting such other and further relief as the Court shall deem just and proper.

Dated: May 27, 2003

Respectfully submitted,

By: Stephen Colangelo

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Attorneys for Plaintiff
THE REGENTS OF THE UNIVERSITY OF
CALIFORNIA

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

**INITIAL ELECTRONIC CASE FILING
ORDER**

CASE NUMBER 1:03CV01133

JUDGE: Richard W. Roberts

DECK TYPE: General Civil

DATE STAMP: 05/27/2003

This case has been designated for the Court's Electronic Case Filing (ECF) Program and this order will be docketed in that case.

ORDERED: that counsel shall:

- **File** within **24 hours**, the initial pleading in this case, in Portable Document Format (PDF) on a disk, or e-mail the filing to: **dcd_cmecf@dcd.uscourts.gov**. Counsel must also serve this Order and the e-filer registration forms on all parties in the case.
- **Register** to become an electronic filer by completing the ECF registration form and returning it to the Court. The Clerk's Office will EMail your ECF login ID and Password. If counsel has already registered in another case, do not register again.
- Electronically **File** all subsequent papers in this case.
- Have a **PACER** account (Public Access to Court Electronic Records), in order to view dockets and documents. If your office already has a PACER account, use that account. It is not necessary to have a CM/ECF account to view documents. Call 800-676-6856 or visit **www.pacer.psc.uscourts.gov** for additional information.
- **Check** the docket by entering the Court's CM/ECF Internet site (**www.dcd.uscourts.gov**), clicking on the **Case Management/Electronic Case Filing System** hyperlink, and logging in with your **PACER** login and password. Counsel is accountable for updates to the case.
- **Schedule training** within three weeks after the date of the initial filing. Contact Will Short at (202) 354-3297 or Joe Burgess at (202) 354-3172, to schedule training. Filing instructions and an interactive tutorial can be found by entering the Court's Internet site (**www.dcd.uscourts.gov**) and clicking on the hyperlink to **Electronic Case Filing**.

ROBERTS, J. RWR

United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELECTRONIC CASE FILES
Attorney/Participant Registration Form

LIVE SYSTEM

This form shall be used to register for an account on the Court's Electronic Case Files (ECF) system and to subscribe to the ECF EMail (Listserver) notification service. Registered attorneys and other participants will have privileges both to electronically submit documents, and to view and retrieve electronic docket sheets and documents for all cases assigned to the Electronic Case Files system. Listserver subscribers receive email messages whenever the Court wishes to electronically notify ECF registrants of pertinent ECF information.

The following information is required for registration:

First/Middle/Last Name _____

Last four digits of Social Security Number _____

DC Bar ID#: _____

Firm Name: _____

Firm Address: _____

Voice Phone Number: _____

FAX Phone Number: _____

Internet E-Mail Address: _____

By submitting this registration form, the undersigned agrees to abide by the following rules:

1. This system is for use only in cases permitted by the *U.S. District Court for the District of Columbia*. It may be used to file and view electronic documents, docket sheets, and notices. Please contact Will Short at 202-354-3297 or Joe Burgess at 202-354-3172, to schedule training.
2. Pursuant to Federal Rule of Civil Procedure 11, every pleading, motion, and other paper (except list, schedules, statements or amendments thereto) shall be signed by at least one attorney of record or, if the party is not represented by an attorney, all papers shall be

signed by the party. An attorney's/participant's password issued by the court combined with the user's identification, serves as and constitutes the attorney's/participant's signature. Therefore, an attorney/participant must protect and secure the password issued by the court. If there is any reason to suspect the password has been compromised in any way, it is the duty and responsibility of the attorney/participant to immediately notify the court. This should include the resignation or reassignment of the person with authority to use the password. The Court will immediately delete that password from the electronic filing system and issue a new password.

3. An attorney's/participant's registration will not waive conventional service of a summons and complaint, subpoena, or other judicial process; submit the client to the jurisdiction of the Court; or operate as a consent to accept service of pleadings, documents, and orders in actions in which such attorney/participant has not entered an appearance. An attorney's/participant's registration will constitute a waiver in law only of conventional service of other non-process pleadings, documents, and orders in the case. The attorney/participant agrees to accept, on behalf of the client, service of notice of the electronic filing by hand, facsimile or authorized e-mail.
4. Attorneys must be active members of the bar of this Court to file pleadings electronically.

Please return this form to:

U.S. District Court for the District of Columbia
Attn: Attorney Admissions
333 Constitution Avenue NW, Room 1825
Washington, DC 20001

Or FAX to:

Will Short
U.S. District Court for the District of Columbia
(202) 354-3023

Applicant's Signature

Full Last Name

Initial of
First Name

Last 4 Digits SS#

United States District Court for the District of Columbia

Electronic Case Filing (ECF)

Congratulations! This case has been selected for Electronic Case Filing (ECF) and is now part of a new and exciting electronic case filing project. Using the Internet, ECF provides access to docket sheets and to most case documents. With ECF, documents may also be filed electronically over the Internet. Prospective users may go to the Court's ECF WebPage at <http://www.dcd.uscourts.gov/ecf.html> to learn more about ECF, view the ECF Users Manual, and conduct an ECF tutorial. Also, the Clerk's office provides training on the proper use of ECF and its procedures. If you wish to schedule ECF training, please contact Will Short at 202-354-3297 or Joe Burgess at (202) 354-3172.

How Do I File Electronically?

Attorneys gain access to the Court's ECF system via the Internet and identify themselves by entering a Court-assigned user identification name and password. Next, attorneys must enter the case number for which their document is being filed, the name of the party for whom the document is being filed, and the type of document being submitted (motion, answer, reply, etc.). Then, the document is transmitted to the Court's server.

What Equipment Do I Need?

- A personal computer
- An Internet connection
- Netscape Navigator Version 4.X or Microsoft Explorer 5.X
- Adobe Acrobat (Version 3.0 or higher) or WordPerfect (Version 9.0 or 10.0)
- Document Scanner

How Do I Get Trained On ECF?

ECF Training is conducted every Tuesday and Thursday

- Times: 10AM or 2PM
- Duration: 1 to 2 hours
- Location: U.S. District Courthouse, First Floor
- Contact Will Short at 202-354-3297 or Joe Burgess at (202) 354-3172 to schedule training.

Who Do I Contact If I Have Questions About ECF?

- | | |
|--------------------------------------------|--------------|
| • Greg Hughes, Chief Deputy for Operations | 202-354-3191 |
| • Angela Caesar-Mobley, Operations Manager | 202-354-3181 |
| • Joe Burgess, Operations Manager | 202-354-3172 |
| • Will Short, Technical Writer | 202-354-3297 |

**The United States District Court
for the
District of Columbia**

Presents

ELECTRONIC CASE FILING TRAINING

**Every Tuesday and Thursday
10AM – 11:30AM
or
2PM – 3:30PM**

The United States District Court for the District of Columbia is directing attorneys to file documents electronically over the Internet in selected civil cases using the Court's new Electronic Case Filing (ECF) system. Eventually, all new civil cases filed with the Court will be ECF cases. In order to prepare attorneys for ECF, the Clerk's office is conducting ECF training classes every Tuesday and Thursday at the U.S. District Courthouse, 333 Constitution Avenue NW. Classes convene at 10 AM and 2 PM.

After completing an ECF class, attending attorneys and their staff will have sufficient knowledge and skills to successfully use the Electronic Case Filing system. ECF instructional topics include:

- Preparing documents for electronic filing
- Electronically filing documents
- Retrieving electronically filed documents
- Receiving notification of electronic filings
- Seeking help with electronic filing

Please call Will Short at 202-354-3297 or Joe Burgess at 202-354-3172 to schedule a training date and time at the District Courthouse. Seating is limited. Also, the Clerk's office will deliver offsite training for attorneys and law firms at other times and locations. Contact Will Short or Joe Burgess to discuss such an arrangement and the system requirements for offsite training.